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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/633,232

Applicant(s)

DIERYNCK ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,12-17 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,12,13,15 and 16 is/are rejected.
- 7) ☒ Claim(s) 7,14,17 and 36-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-6, 8-9, 12-13, and 15-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Griffiths et al (U.S. Patent No. 5,612,016), for reasons of record set forth in Paper No.8, mailed 1/28/03. Applicants' arguments filed 7/28/03 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant argues that the definition of "apo metal binding protein" from the specification refers to any protein or peptide that, inter alia, binds itself to a metal, and that in contrast, the '016 patent describes a protein that is to be conjugated to a chelating agent so that such chelating agent in the conjugated protein-agent entity can bind to a metal, rather than the non-conjugated protein itself. It is argued that the '016 patent does not disclose proteins that are capable by themselves to bind to a metal, absent conjugation with a chelating agent.

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This argument is not persuasive for the following reasons. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., proteins that are capable by themselves to bind to a metal, absent conjugation with a chelating agent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are drawn to apo metal binding proteins. The definition of "apo metal binding protein" has no limitation to "capable by themselves to bind to a metal, absent conjugation with a chelating agent". The term is defined more broadly in the specification to read on "any protein or peptide that acquires a detectable color upon the binding of one or more metal ions or changes in color upon binding of a metal ion or an additional metal ion". A molecule that comprises a protein or peptide and a conjugated chelating agent is still a protein or peptide because it comprises an amino acid sequence linked together by peptide bonds. This molecule taught by the cited reference, which is a protein or peptide comprising the conjugated chelating agent, acquires a detectable color upon the binding of one or more metal ions, and thus the molecule reads

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on apo metal binding protein as specifically defined by the specification. Therefore, it is proper that the rejection be maintained.

Claim Rejections - 35 USC § 103

Claims 1-6, 8-10, 12-13, and 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al (U.S. Patent No. 5,612,016), for reasons of record set forth in Paper No.8, mailed 1/28/03. Applicants' arguments filed 7/28/03 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant refers to the same argument set forth above as being applicable to the instant rejection and thus the same response to the argument is equally applicable.

The applicant also argues that the '016 patent does not suggest or provide motivation for the claimed methods because problems that are solved by the claimed methods, such as problems derived from extra manipulations, are not addressed by the methods described in the '016 patent, and reliance on protein-chelating agent conjugation as in the '016 patent is not necessitated by the claimed methods.

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This argument is not persuasive for the following reasons. First, the claims read on the proteins and methods taught by the cited reference for the reasons described above and thus there isn't anything different "solved" by the claims which is different from what is taught in the '016 patent. The instant rejection was not based upon "solving" the problems solved by the claimed methods, but instead merely to show the obviousness of claim 10 based upon the cited reference (providing the apo metal binding protein to a cell in vitro). The other rejected claims were also rejected under 35 USC 102(b), included because it is Office policy to do so in rejections under 103(a) (done to reject dependent claim(s) needed because of additional claim limitations not explicitly covered by the rejection under 35 USC 102, but obvious under 35 USC 103(a)) based upon the same reference used in a rejection under 35 USC 102. Second, the argument that reliance on protein-chelating agent conjugation as in the '016 patent is not necessitated by the claimed methods is not a persuasive argument in overcoming the instant rejection because that is not a limitation in the claims. The claims read on the proteins and methods disclosed by the cited reference and thus arguments drawn to non-existent limitations are not persuasive. Therefore, it is proper that the rejection be maintained.

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Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 36-38 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 7, 14, and 17. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). This is a new objection necessitated by the applicant's amendment filed 7/28/03.

In the instant case, claims 36-38 are independent (or new dependent) versions of claims 7, 14, and 17 and thus cover identical scopes. Therefore, they are duplicate claims.

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Allowable Subject Matter

Claims 7, 14, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

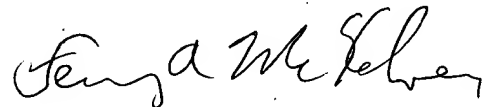
Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

November 2, 2003